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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,943	05/03/2006	Daniel C. Carter	P07931US06/BAS	5248
881 7590 09/11/2008 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER BORIN, MICHAEL L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 09/11/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,943

Applicant(s)

CARTER ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 12-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/02)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-10, 12-34 are pending

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10,12-15, drawn to method of evaluating ability to associate with molecule comprising human albumin binding regions. The Group is subject to a further restriction as specified below.

Group II, claim 16, drawn to method for identifying activator/inhibitor of a molecule comprising human albumin binding regions. The Group is subject to a further restriction as specified below..

Group III, claims 17-19, drawn to method for identifying ligand interaction with a molecule comprising human albumin binding regions. The Group is subject to a further restriction as specified below..

Group IV, claim 20, drawn to method for optimizing binding of a compound to human serum albumin. The Group is subject to a further restriction as specified below.

Group V, claims 21-23, drawn to method of producing database of 3-D coordinates. The Group is subject to a further restriction as specified below..

Group VI, claims 24-27, drawn to method of producing database of albumin-binding compounds. The Group is subject to a further restriction as specified below.

Group VII, claim 28, drawn to polypeptide comprising human albumin binding regions. The Group is subject to a further restriction as specified below..

Group VIII, claims 29-34, drawn to method for determining binding affinity to human serum albumin domain. The Group is subject to a further restriction as specified below.

This application contains the following groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group VII is the technical feature that links Groups I to VIII. Group VII is not the contribution over the prior art because it would be suggested by references teaching polypeptides comprising subdomains of human albumin. As such, it would be suggested by a reference teaching human albumin itself as it comprises any of the recited subdomains. Therefore, the lack of unity is present because the linking technical feature is not a "special technical feature" as defined by PCT Rule 13.2. Further, Groups I-VI, VIII are directed to distinct separate methods which do not share a special technical feature because each method

contains specific and unique method steps which are not shared by each of the other methods and each method has a unique and distinct outcome.

Further, each of the Groups is subject to additional restriction the following restriction. This subsequent restriction is detailed for the Group I; the restriction of corresponding claims of any one of the Groups II-VIII is applied for the same reasons.

I.1 Claims 1-5 (in part), and claims 13,14, directed to molecule comprising albumin domain IA.

I.2 Claims 1-5 (in part), and claims 6,7, directed to molecule comprising albumin domain IB.

I.3 Claims 1-5 (in part), directed to molecule comprising albumin subdomain combination IA/IB.

I.4 Claims 1-5 (in part), and claims 8,9, directed to molecule comprising albumin domain IIA.

I.5 Claims 1-5 (in part), directed to molecule comprising albumin subdomain combination IA/IIA.

I.6 Claims 1-5 (in part), directed to molecule comprising albumin subdomain combination I/II.

I.7 Claims 1-5 (in part), directed to molecule comprising albumin subdomain combination II/III.

I.8 Claims 1-5 (in part), directed to molecule comprising albumin domain IIB.

I.9 Claims 1-5 (in part), and claim 15, directed to molecule comprising albumin subdomain combination IIA/IIB.

I.10 Claims 1-5 (in part), and claims 10,12, directed to molecule comprising albumin domain IIIA.

I.11 Claims 1-5 (in part), directed to molecule comprising albumin domain IIIB.

I.12. Claims 1-5 (in part), directed to molecule comprising albumin subdomain combination IIIA/IIIB.

I.13 Claims 1-5 (in part), directed to molecule comprising albumin domain IIIB'.

For groups directed to molecules addressed as comprising single albumin domain (e.g., comprising domain IA vs. domain I) the groups are directed to methods that do not relate to a single general inventive concept under PCT Rule 13.1 because the methods are directed to methods of evaluating structurally distinct products – i.e., polypeptides having unrelated structure – that do not overlap in scope, and the inventions as claimed are not obvious variants. There is nothing of record to show them to be obvious variants.

The same applies to groups directed to molecules addressed as comprising combinations of albumin domains (e.g., IA/IIA vs. IIA/IIIB), because the methods are directed to methods of evaluating structurally distinct products – i.e., polypeptides

having unrelated structure – that do not overlap in scope, and the inventions as claimed are not obvious variants.

With regard to Groups directed to molecules addressed as comprising combinations of albumin domains vs. molecules addressed as comprising single albumin domain (e.g., Groups IA and IB vs group I.3) , the inventions are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. When subcombinations are separately claimed along with a claimed combination, the presence of each subcombination claim may be used as evidence that the combination does not require either subcombination for its patentability. MPEP 806.05(d). If either of Groups directed to subcombinations (IA and IB in the above example) is elected and found allowable, claims to combination IA/IB would be considered for rejoinder. See MPEP 821.04(a).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Borin, Ph.D./
Primary Examiner, Art Unit 1631
